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10/501,623	07/15/2004	Philippe Moussou	C 2319 PCT/US	2222

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EXAMINER	
MI, QIUWEN	
ART UNIT	PAPER NUMBER
1655	
MAIL DATE	DELIVERY MODE
04/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,623	MOUSSOU ET AL.	
	Examiner	Art Unit	
	QIUWEN MI	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41,43-48,53,54 and 56-62* is/are pending in the application.

4a) Of the above claim(s) *57-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41,43-48,53,54,56,61 and 62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment in the reply filed on 2/20/08 is acknowledged. Any rejection not reiterated is hereby withdrawn.

Claims Pending

Applicant has cancelled claims 1-40, 42, 49-52, and 55. Claims 41, 43-48, 53, 54, and 56-62 are pending. Claims 57-60 are withdrawn. Claims 41, 43-48, 53, 54, 56, 61, and 62 are examined on the merits.

Claim Rejections –35 USC § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41, 43-48, 53, 54, 56, 61, and 62 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 11/28/2007, repeated below, slightly altered to take into consideration Applicant's amendment filed on 2/20/08. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

The metes and bounds of claim 41 and 56 are rendered vague and indefinite by term "extract" because this term, in and of itself, does not adequately delineate its metes and bounds. An "extract" is only defined by the process of its preparation. Such product-by-process claims are intended to define products which are otherwise difficult to define and/or distinguish from the prior art except by the process of making. Since any given biological source contains thousand of extractable compounds, each with it's own particular extraction properties, the nature of resulting "extract" will depend on the conditions of the extraction and solvent used. For example, at what temperature is the extraction performed; is the extract of a biological source with one of various distinct solvents has a profound impact on the final product with respect to the presence, amounts, and/or ratios of active ingredients obtained, and, thus, on the ability of the "extract" to provide the desired functional effects(s) claimed and/or disclosed. Since the "extract" itself is clearly essential to the instantly claimed invention, the steps(s) by which the claimed "extract" is/are obtained is/are also clearly essential and, therefore, must be recited in the claims (i.e., as a product-by-process). Although the claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., *In re* Van Guens, 988 F.2d 1181, 26 PSPG2d 1057 (Ded. Cir. 1991)). Accordingly, without the recitation of all these critical limitations as set forth above, the claims do not adequately define the instant invention.

Claims 41 and 56 recite "rice plant extract", and the metes and bound of those claims are uncertain because it is unclear as to the identification of the ingredients to which Applicant intends to direct the subject matter. Although the use of common names or traditional/ethnopharmacological names is permissible in patent applications, the standard Latin

genus-species name of each ingredient should accompany non-technical nomenclature as a means for identifying the subject botanical and animal matter noted in this application. Applicant may overcome the rejection by placing the genus-species name of "X" in parentheses after the term (s) "X". Please make sure to write the Latin name in the proper format, wherein the first word is capitalized, the second word is lowercase and the entire name is italicized.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Applicant argues that the extract is not necessarily critical or essential to the invention. The extract or a plant constituent may be included in the fermentation broth.

This is not found persuasive. Since claim 42 recites "rice plant extract", it is crucial that Applicant indicates the type of the rice plant extract, for instance, hot water extract of rice plant, so that one of the ordinary skills in the art would know what kind of constituents is in the fermentation broth.

Applicant argues that the latin genus-species name is not required in non-plant patent application.

As indicated above, the standard Latin genus-species name of each ingredient should accompany non-technical nomenclature as a means for identifying the subject botanical and animal matter noted in this application.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 41, 43-48, 53, 54, 56, 61, and 62 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sawaki et al (US 2004/0052759), in view of Uno et al (US 2001/0041203) and Miyazaki et al (US 7,090,875), further in view of Klaenhammer et al (US 5,618,723).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 11/28/2007, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Sawaki et al teach cosmetics containing an active component comprising lactic acid bacteria fermented rice obtained by fermenting rice with lactic acid bacteria (see Abstract). Sawaki et al also teach that lactic acid bacteria to be used for fermentation of such raw rice include, for example, *Lactobacillus*, and *Streptococcus* (the same as *lactococci*, see Klaenhammer et al (US 5,618,723), col 10, line 1-5) *faecallis* etc [0016]). Sawaki et al further teach that the cosmetics can be obtained, which are excellent in emulsion stability and biological safety, have a good feeling when using and after using and further have a total beautifying effect of cosmetic treatment including an improving effect on hair texture, and brightening and caring effects on the skin (see Abstract).

Sawaki et al do not teach the claimed pH, pretreatment, temperature, and separation method, and Sawaki et al do not teach that Leuconostoc, and yeast are used in fermenting rice.

Uno et al teach adding water and yeast to rice, heating at 90°C for 30 min (pretreatment), fermenting at 20°C for 2 days, and then being filtered [0129; 0130]. Uno et al also teach that the invention being used in cosmetics [0076; 0077; 0079; 0080]. Uno et al also teach that liquefying process (pretreatment) can facilitate fibrous hydrolase activity and ferulic acid esterase activity, and contribute to decomposition of fibers in cereals and liberation of ferulic acid [0071] which can be further used in cosmetics [0076].

Miyazaki et al teach a fermented product prepared by microorganisms such as lactobacillus, lactococcus, and leuconostoc, or by several kinds of strains in combination at pH preferably 5.0-6.0 (col 5, lines 50-55). Miyazaki et al also teach that the fermented product can improve dry, roughed, wrinkled, or loosened skin and prevent the skin from aging (col 2, lines 47-55).

Klaenhammer et al teach that bacterial used in the fermentation of dough formed from cereals (e.g., wheat, rye, rice, oats, barley, and corn) include yeasts such as *Saccharomyces cerevisiae* and *Candida utilis*, and lactic acid bacterial of genera Lactobacillus, Lactococcus, Leuconostoc etc (col 9, lines 42-48).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the pretreatment, and the separation (filtering) method of Uno and the pH of Miyazaki et al in Sawaki et al for the following reasons.

It is clear from Uno et al that liquefying process (pretreatment) can facilitate fibrous hydrolase activity and ferulic acid esterase activity, and contribute to decomposition of fibers in cereals and liberation of ferulic acid [0071] which can be further used in cosmetics [0076], therefore it is obvious for one of ordinary skill in the art at the time the invention was made to follow the procedure of Uno et al in Sawaki et al to make the fermented rice extract so that the rice fermentation product in Sawaki et al can be used in cosmetics.

It is further clear from Miyazaki et al that keeping the fermented product at pH 5-6 suits for cosmetic skin application in cosmetic products, therefore it is obvious for one of ordinary skill in the art at the time the invention was made to use the pH of Miyazaki et al in the fermented product in Sawaki et al to achieve the antiaging effect in cosmetics.

Since all the inventions of Sawaki et al, Uno et al and Miyazaki et al yielded beneficial results in the cosmetic industry, one of ordinary skill in the art would have been motivated to make the modifications.

It would be obvious to combine lactobacillus, lactococcus, leuconostoc, and yeast together to enhance the fermenting effect, as Klaenhammer et al teach each of them individually as examples in the fermentation preparations. Since Klaenhammer et al only teach fermentation of rice etc include yeasts such as *Saccharomyces cerevisiae* and *Candida utilis*; and lactic acid bacteria of genera *Lactobacillus*, *Lactoccus*, *Pediococcus* and *Leuconostoc*, thus choosing from a finite number of predictable solutions (choosing from three genus out of four) would have been obvious because a person of ordinary skill has good reason to pursue the known options with his

or her technical grasps. If this leads to the anticipated success, it is likely the product not of innovation, but of ordinary skill and common sense.

Regarding determining the pH of the fermented product, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, depending upon the types and the amounts of the bacteria used for fermentation.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that none of the cited references discloses or teaches the specific combination of microorganisms comprising at least one Lactobacillus, at least one Lactococcus, at least one Leuconostoc, and at least one yeast (page 8, 2nd paragraph), no such express or implied teaching exists, either in Sawaki, Uno, Miyazaki, or Klaenhammer, or the combination thereof, to specifically select and combine at least one Lactobacillus, at least one Lactococcus, at least one Leuconostoc, and at least one yeast (page 8, last paragraph).

Applicant argues that there is no specific suggestion or teaching in the references to combine prior art. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of invention. In addition, KSR forecloses the argument that a specific teaching, suggestion, or motivation is

required to support a finding of obviousness. See the recent Board decision Ex parte Smith, --USPQ2d--, slip op. at 20 (Bd. Pat. App.& Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396) (available at http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf).

Applicant argues that no convincing line of reasoning is provided by the Examiner as to why the combination would have been obvious, and the Examiner only cited references using Applicant's claims as a guide, and it would not have been obvious for the skilled worker to selectively pick and choose among the cited reference to arrive at the particular combination as claimed (page 9, 2nd paragraph).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In addition, there is a clear line of reasoning in using the cited references. As indicated above, since Sawaki et al, Uno et al, and Miyazaki et al use claimed components (Lactobacillus, Lactococcus, and Leuconostoc, yeast, and rice) individually in cosmetic industry, one of the ordinary skills in the art would have been motivated to combine Lactobacillus, Lactococcus, and Leuconostoc, yeast, and rice and use them together in cosmetic.

Applicant argues that Examiner fails to adequately explain why one skilled in the art would have chosen among the various genera of Klaenhammer, or any of the individual references or the combination thereof (page 9, 3rd paragraph), and there is no disclosure by Klaenhammer to use a mixture of any of the Lactobacillus, Lactococcus, pediococcus, or Leuconostoc in the fermentation of rice (page 9, 3rd. paragraph).

This is not found persuasive. As pointed out previously, on column 9, lines 42-48, Klaenhammer states "bacterial used in the fermentation of dough formed from cereals (e.g., wheat, rye, **rice**, oats, barley, and corn) include yeasts such as *Saccharomyces cerevisiae* and *Candida utilis*, and lactic acid bacterial of genera Lactobacillus, Lactococcus, Pediococcus, Leuconostoc etc". The only species that is not in the current claim is Pediococcus. Thus, choosing from a finite number of predictable solutions (choosing from three genus out of four) would have been obvious because a person of ordinary skill has good reason to pursue the known options with his or her technical grasps. If this leads to the anticipated success, it is likely the product not of innovation, but of ordinary skill and common sense.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Qiuwen Mi

/Michele Flood/

Primary Examiner, Art Unit 1655